IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MALLINCKRODT HOSPITAL PRODUCTS IP LIMITED, MALLINCKRODT HOSPITAL PRODUCTS INC., and NEW PHARMATOP L.P.,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
BAXTER HEALTHCARE CORPORATION,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Mallinckrodt Hospital Products IP Limited, Mallinckrodt Hospital Products Inc., and New Pharmatop L.P. (collectively "Plaintiffs"), by their attorneys, file this Complaint for patent infringement against Defendant Baxter Healthcare Corporation ("Defendant" or "Baxter") and allege as follows:

THE PARTIES

1. Plaintiff Mallinckrodt Hospital Products IP Limited ("Mallinckrodt Hospital Products IP") is a company organized and existing under the laws of Ireland, having a registered address of College Business & Technology Park, Cruiserath Road, Blanchardstown, Dublin 15, D15 TX2V, Ireland. Mallinckrodt Hospital Products IP is a wholly-owned subsidiary of Mallinckrodt plc. As set forth herein, Mallinckrodt Hospital Products IP is the assignee of U.S. Patent No. 9,399,012 ("'012 patent"), U.S. Patent No. 9,610,265 ("'265 patent"), U.S. Patent No. 9,987,238 ("'238 patent"), and U.S. Patent No. 10,383,834 ("'834 patent") and is the exclusive sub-licensee of U.S. Patent No. 6,992,218 ("'218 patent") (collectively, "Patents-in-Suit").

2. Plaintiff Mallinckrodt Hospital Products Inc. ("Mallinckrodt Hospital Products"), formerly Cadence Pharmaceuticals, Inc. ("Cadence"), is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 675 McDonnell Blvd., Hazelwood, Missouri 63042. Mallinckrodt Hospital Products is a wholly-owned subsidiary of Mallinckrodt plc.

3. Plaintiff New Pharmatop L.P. ("New Pharmatop") is a Delaware limited partnership having its registered agent c/o Corporation Services Company, 2711 Centerville Road, Suite 400, Wilmington, Delaware. As set forth herein, New Pharmatop is the current assignee of the '218 patent.

4. On information and belief, Defendant Baxter Healthcare Corporation is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at One Baxter Parkway, Deerfield, Illinois 60015. On information and belief, Baxter manufactures, markets, distributes, and/or sells generic pharmaceutical products for use throughout the United States, including in this judicial district.

NATURE OF THE ACTION

5. This is a civil action for infringement of the Patents-in-Suit pursuant to the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*; the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. §§ 301 *et seq.*; and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq.*

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a), and 2201(a).

7. This Court has personal jurisdiction over Baxter because, *inter alia*, it: (1) is incorporated in Delaware; (2) has submitted Abbreviated New Drug Application ("ANDA")

No. 214331 (the "Baxter ANDA"), claiming bioequivalence to Plaintiffs' OFIRMEV® injectable acetaminophen product, seeking nationwide approval of its proposed product; and (3) through the submission of its ANDA, intends to commercially manufacture, use, import, market, offer for sale, and sell the Baxter ANDA product throughout the United States, including in this judicial district.

8. Venue is proper in this Court pursuant to 28 U.S.C. § 1400(b).

9. This action involves patents that have already been at issue in prior actions before this Court. The '218 patent was at issue in the following exemplary actions: *Cadence Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC*, No. 11-733; *Cadence Pharmaceuticals, Inc. v. InnoPharma Licensing LLC*, No. 14-1225; *Mallinckrodt IP v. Mylan Laboratories Ltd*., No. 14-1499; *Mallinckrodt IP v. B. Braun Medical Inc*., No. 17-365; and *Mallinckrodt IP v. Altan Pharma Ltd.*, No. 19-552. The '012 Patent was previously at issue before this Court in the actions captioned *Mallinckrodt IP v. InnoPharma Licensing LLC*, No. 16-1116; *Mallinckrodt IP v. Mylan Laboratories Ltd.*, No. 16-1115; *Mallinckrodt IP v. B. Braun Medical Inc.*, No. 17-365 and *Mallinckrodt IP v. Altan Pharma Ltd.*, No. 19-552. The '265 patent was previously at issue before this Court in the actions captioned *Mallinckrodt IP v. B. Braun Medical Inc.*, No. 17-660 and *Mallinckrodt IP v. Altan Pharma Ltd.*, No. 19-552. The '238 patent was previously at issue before this Court in the actions captioned *Mallinckrodt IP v. B. Braun Medical Inc*., No. 18-1090 and *Mallinckrodt IP v. Altan Pharma Ltd.*, No. 19-552.

THE PATENTS-IN-SUIT

10. The '218 patent, titled "Methods for Obtaining Aqueous Formulations of Oxidation-Sensitive Active Principles," was duly and legally issued by the United States Patent and Trademark Office ("PTO") on January 31, 2006. Named inventors Francois Dietlin and

Daniele Fredj assigned the application which issued as the '218 patent to SCR Pharmatop ("Pharmatop").

11. Pharmatop, which subsequently assigned the '218 patent to New Pharmatop, granted an exclusive license to the '218 patent to Bristol-Myers Squibb Company ("BMS") with a right to sublicense. BMS granted Cadence (now Mallinckrodt Hospital Products) a sublicense, which was exclusive even to BMS, to the '218 patent with regard to all rights pertinent hereto. As a result of the corporate restructuring following the purchase of Cadence by Mallinckrodt plc, Mallinckrodt Hospital Products IP is the exclusive sub-licensee of the '218 patent. A true and correct copy of the '218 patent is attached as Exhibit A.

12. Claim 1 of the '218 patent recites: "[a] method for preparing an aqueous solution with an active nature susceptible to oxidation, which is paracetamol, while preserving for a prolonged period, comprising deoxygenation of the solution by bubbling with at least one inert gas and/or placing under vacuum, until the oxygen content is below 2 ppm, and optionally the aforementioned aqueous solution with an active principle is topped with an inert gas atmosphere heavier than air and placed in a closed container in which the prevailing pressure is 65,000 Pa maximum, and the oxygen content of the aqueous solution is below 2 ppm, and optionally the deoxygenation of the solution is completed by addition of an antioxidant."

13. The '012 patent, titled "Reduced Dose Intravenous Acetaminophen," was duly and legally issued by the PTO on July 26, 2016. Named inventors Mike Allan Royal and James Bradley Breitmeyer assigned the application that issued as the '012 patent to Cadence, which subsequently assigned that application to Mallinckrodt IP, which subsequently changed its name to Mallinckrodt IP Unlimited Company ("Mallinckrodt IP Unlimited"), which subsequently assigned that application to Mallinckrodt Hospital Products IP. Mallinckrodt Hospital Products

IP is now the sole assignee of the ’012 patent. A true and correct copy of the ’012 patent is attached as Exhibit B.

14. Claim 1 of the ’012 patent recites “[a] method for the treatment of pain or fever in an adult human or an adolescent human subject weighing at least 50 kg, in need thereof, comprising administering to the subject, by an intravenous route of administration, a therapeutically effective amount of a pharmaceutical composition comprising about 550 mg to about 800 mg of acetaminophen; and repeating said administration at least once at an interval of about 3 to about 5 hours.”

15. The ’265 patent, titled “Reduced Dose Intravenous Acetaminophen,” was duly and legally issued by the PTO on April 4, 2017. Named inventors Mike Allan Royal and James Bradley Breitmeyer assigned the application that issued as the ’265 patent to Cadence, which subsequently assigned that application to Mallinckrodt IP, which subsequently changed its name to Mallinckrodt IP Unlimited, which subsequently assigned that application to Mallinckrodt Hospital Products IP. Mallinckrodt Hospital Products IP is now the sole assignee of the ’265 patent. A true and correct copy of the ’265 patent is attached as Exhibit C.

16. Claim 1 of the ’265 patent recites “[a] method of treating pain in a human subject weighing at least 50 kg comprising: co-administering to the subject a therapeutically effective amount of a first pharmaceutical composition comprising about 500 mg to about 750 mg of acetaminophen and a therapeutically effective amount of a second pharmaceutical composition comprising an opioid analgesic; wherein the first pharmaceutical composition is administered to the subject intravenously.”

17. The ’238 patent, “Reduced Dose Intravenous Acetaminophen,” was duly and legally issued by the PTO on June 5, 2018. Named inventors Mike Allan Royal and James

Bradley Breitmeyer assigned the application that issued as the '238 patent to Cadence, which subsequently assigned that application to Mallinckrodt IP, which subsequently changed its name to Mallinckrodt IP Unlimited, which subsequently assigned that application to Mallinckrodt Hospital Products IP. Mallinckrodt Hospital Products IP is now the sole assignee of the '238 patent. A true and correct copy of the '238 patent is attached as Exhibit D.

18. Claim 1 of the '238 patent recites "[a] method of treating pain in a human subject, in need thereof, weighing at least 50 kg comprising: administering to the subject a therapeutically effective amount of a pharmaceutical composition comprising about 500 mg to about 750 mg of acetaminophen; and repeating the administration at least once every four hours; wherein the pharmaceutical composition is administered to the subject intravenously; and wherein the therapeutic effect of the pharmaceutical composition is comparable to the standard of care treatment of 1000 mg of acetaminophen administered orally every 6 hours."

19. The '834 patent, titled "Reduced Dose Intravenous Acetaminophen," was duly and legally issued by the PTO on August 20, 2019. Named inventors Mike Allan Royal and James Bradley Breitmeyer assigned the application that issued as the '834 patent to Mallinckrodt Hospital Products IP. Mallinckrodt Hospital Products IP is now the sole assignee of the '834 patent. A true and correct copy of the '834 patent is attached as Exhibit E.

20. Claim 1 of the '834 patent recites "[a] method of treating pain in a human subject weighing at least 50 kg comprising: administering to the subject an intravenous acetaminophen formulation comprising about 650 mg of acetaminophen; and repeating the administration of the intravenous acetaminophen formulation every four hours; wherein the subject receives a maximum daily dose of less than 4000 mg of acetaminophen per day."

OFIRMEV®

21. Cadence obtained approval from the FDA for NDA No. 022450 for OFIRMEV®, the first and only intravenous (IV) formulation of acetaminophen available in the United States. As part of the corporate restructuring resulting from the purchase of Cadence by Mallinckrodt plc, Mallinckrodt Hospital Products IP is now the holder of NDA No. 022450. Mallinckrodt Hospital Products distributes OFIRMEV®.

22. OFIRMEV® was approved by the FDA on November 2, 2010. OFIRMEV® is indicated for the management of mild to moderate pain, management of moderate to severe pain with adjunctive opioid analgesics, and reduction of fever.

23. The publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") identifies drug products approved on the basis of safety and effectiveness by the FDA under the Federal Food, Drug, and Cosmetic Act pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations. Each of the '218, '012, '265, '238, and '834 patents were timely listed in the Orange Book with respect to OFIRMEV®.

24. Based on revisions made to the OFIRMEV® package insert based on data from a randomized, placebo controlled, multicenter study of intravenous acetaminophen for the treatment of acute pain in pediatric patients to fulfill a post-marketing requirement, OFIRMEV® was granted exclusivity until July 27, 2020.

25. On information and belief, no application referencing OFIRMEV® as a reference listed drug will be finally approved until after the expiration of said exclusivity in July 2020.

BAXTER'S INFRINGEMENT OF THE PATENTS-IN-SUIT

26. On information and belief, Baxter submitted the Baxter ANDA to the FDA under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(b)(2)), seeking approval to engage

in the commercial manufacture, use, sale or offer for sale, and/or importation of the Baxter ANDA product prior to the expiration of the '218, '012, '265, '238, and '834 patents, which are listed in the Orange Book with respect to OFIRMEV®.

27. By a letter dated February 19, 2020, and received after that date (the "Baxter Letter"), Baxter stated that it submitted the Baxter ANDA seeking approval to engage in the commercial manufacture, use, sale or offer for sale, and/or importation of the Baxter ANDA product prior to the expiration of the '218 patent.

28. The Baxter Letter also states that the Baxter ANDA contains a certification under 21 U.S.C. § 355(j)(2)(B)(iv)(II) (the "Paragraph IV certification") alleging that the '218 patent is "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the drug product described in Baxter's ANDA."

29. Baxter's submission of the Baxter ANDA to the FDA, including its Paragraph IV certification, constitutes an act of infringement of the '218 patent under 35 U.S.C. § 271(e)(2)(A). In the event that Baxter commercially manufactures, imports, uses, offers for sale, or sells the Baxter ANDA product or induces or contributes to such conduct, said actions would constitute infringement of the '218 patent under 35 U.S.C. § 271(a), (b), and/or (c).

30. On information and belief, the only viable way of preparing an acetaminophen solution with prolonged stability is to deoxygenate the solution (or an equivalent thereof) to below 2 ppm oxygen. For instance, the proposed generic Exela Pharma Sciences product was found by this Court to have infringed claims of the '218 patent, and the Cadence product was deemed to be a commercial embodiment thereof. *See Cadence Pharm., Inc. v. Exela Pharma Scis., LLC*, No. 11-733, 2013 WL 11083853 (D. Del. Nov. 14, 2013), *aff'd*, 780 F.3d 1364 (Fed. Cir. 2015). Both the Exela and Cadence intravenous acetaminophen products are deoxygenated

to below 2 ppm during preparation by bubbling with at least one inert gas and/or placing under vacuum (or an equivalent). *See id.*

31. OFIRMEV® was the first aqueous injectable acetaminophen product approved by the FDA. Accordingly, since November 2, 2010, the only commercially available aqueous injectable acetaminophen product in the United States has employed the invention(s) set forth in various claims of the '218 patent.

32. Wockhardt Bio AG and Agila Specialties Inc. have stipulated to infringement of one or more claims of the '218 patent with regard to their proposed generic versions of OFIRMEV®. *Cadence Pharm., Inc. et al. v. Wockhardt Ltd. et al.*, No. 14-94 (LPS), D.I. 9 (D. Del. Apr. 2, 2014); *Cadence Pharm., Inc. et al. v. Agila Specialties Inc. et al.*, No. 14-1499 (LPS), D.I. 177 (D. Del. Jan. 12, 2017). Thus, those products likewise are deoxygenated to below 2 ppm by bubbling with at least one inert gas and/or placing under vacuum (or an equivalent).

33. A significant number of sophisticated pharmaceutical companies have taken a license to the '218 patent, thereby availing themselves of the invention(s) claimed therein. Thus, BMS, Cadence, Mallinckrodt, Wockhardt, Agila, Paddock Laboratories, Inc., Fresenius Kabi USA, LLC, Sandoz, Inc., B. Braun Medical Inc., Aurobindo Pharma USA, Inc., and Altan Pharma Ltd. each have taken a license to the '218 patent. And Perfalgan, the European counterpart of OFIRMEV®, is deoxygenated to below 2 ppm oxygen by bubbling with at least one inert gas and/or placing under vacuum (or an equivalent). *See Cadence*, 2013 WL 11083853, at *5, *34 n.34.

34. The FDA has approved three other aqueous injectable acetaminophen products that reference OFIRMEV® as the reference listed drug—ANDA products from Sandoz and Paddock (the ANDA for which was subsequently transferred to Custopharm, Inc.), as well as a

505(b)(2) NDA product from Fresenius. Each of those entities has licensed the '218 patent technology, but the licenses do not commence until December 6, 2020. Accordingly, the only FDA-approved aqueous injectable acetaminophen products (the three products above and OFIRMEV® itself) fall under licenses to the '218 patent.

35. On information and belief, and because it is the only viable method of preparing an injectable aqueous solution of acetaminophen, the Baxter ANDA product will be deoxygenated to below 2 ppm oxygen, within the scope of at least one claim of the '218 patent. That dissolved oxygen level will be achieved by bubbling with at least one inert gas and/or placing under vacuum (or an equivalent).

36. Baxter's submission of the Baxter ANDA to the FDA constitutes an act of infringement of the '012 patent under 35 U.S.C. § 271(e)(2)(A). In the event that Baxter commercially manufactures, imports, uses, offers for sale, or sells the Baxter ANDA product or induces such conduct, said actions would constitute infringement of the '012 patent under 35 U.S.C. § 271(a) and/or (b).

37. Under the Hatch-Waxman Act, the evaluation of infringement involves what the applicant will "likely market if its application is approved." *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1248-49 (Fed. Cir. 2000) (citing *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997)).

38. Upon information and belief, *inter alia*, Baxter's proposed labeling will encourage, promote, and/or recommend a method of administering the Baxter ANDA product to treat pain or fever in an adult human or an adolescent human subject weighing at least 50 kg, in need thereof, by administering to the subject, by an intravenous route of administration, a therapeutically effective amount of a pharmaceutical composition comprising about 550 mg to

about 800 mg of acetaminophen and repeating said administration at least once at an interval of about 3 to about 5 hours, which administration will constitute direct infringement of at least Claim 1 of the '012 patent. Upon information and belief, if approved, the Baxter ANDA product will be used to treat mild to moderate pain in adult and pediatric patients two years and older, moderate to severe pain in conjunction with adjunctive opioid analgesics in the same population, and for the reduction of fever in adult and pediatric patients. Upon information and belief, *inter alia*, Baxter will commercially manufacture, import, use, offer for sale, or sell the Baxter ANDA product and recommend usage of the Baxter ANDA product. Upon information and belief, this will occur at Baxter's active behest, and with Baxter's intent, knowledge, and encouragement. Upon information and belief, Baxter will actively induce, encourage, and abet this infringement with knowledge that it is in contravention of the Mallinckrodt Plaintiffs' rights under the '012 patent.

39. The OFIRMEV® labeling includes instructions for administering OFIRMEV® to treat pain or fever in an adult human or an adolescent human subject weighing at least 50 kg, in need thereof, by administering to the subject, by an intravenous route of administration, a therapeutically effective amount of a pharmaceutical composition comprising 650 mg of acetaminophen and repeating said administration at least once at an interval of 4 hours. A true and correct copy of the OFIRMEV® labeling is attached as Exhibit F.

40. On information and belief, Baxter did not perform its own clinical trials, and instead will rely on the clinical trials referenced in the OFIRMEV® labeling for the Baxter ANDA product labeling.

41. Section 6.1 of the OFIRMEV® labeling reports on clinical trials in which patients were administered 650 mg OFIRMEV® every 4 hours. On information and belief, the Baxter

ANDA product labeling will contain the same or substantially the same information concerning said trials.

42. Section 14.1 of the OFIRMEV® labeling describes acute pain studies in adults in which patients were administered 650 mg OFIRMEV® every 4 hours. The OFIRMEV® labeling reports that patients receiving OFIRMEV® experienced a statistically significant greater reduction in pain intensity over 24 hours compared to placebo. On information and belief, the Baxter ANDA product labeling will contain the same or substantially the same statements.

43. The OFIRMEV® labeling therefore instructs, recommends, promotes, and/or encourages medical care providers to practice the methods of at least Claim 1 of the '012 patent. On information and belief, the Baxter ANDA product labeling will instruct, recommend, promote, and/or encourage medical care providers to practice the methods of at least Claim 1 of the '012 patent.

44. The foregoing information in the OFIRMEV® labeling is essential for the safe and effective use of the drug, particularly given the warnings in the labeling concerning potential dosing errors. As the warning in the Highlights of Prescribing Information indicates, "[t]ake care when prescribing, preparing, and administering OFIRMEV Injection to avoid dosing errors which could result in accidental overdose and death." The Highlights continue: "Acetaminophen has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed the recommended maximum daily limits . . . ."

45. Upon information and belief, the Baxter ANDA product will be administered to treat pain or fever in an adult human or an adolescent human subject weighing at least 50 kg, in need thereof, by administering to the subject, by an intravenous route of administration, a

therapeutically effective amount of a pharmaceutical composition comprising about 550 mg to about 800 mg of acetaminophen and repeating said administration at least once at an interval of about 3 to about 5 hours, which administration will constitute direct infringement of at least Claim 1 of the '012 patent. Upon information and belief, this will occur at Baxter's active behest, and with Baxter's intent, knowledge, and encouragement. Upon information and belief, Baxter will actively induce, encourage, and abet this infringement with knowledge that it is in contravention of the Mallinckrodt Plaintiffs' rights under the '012 patent.

46. Baxter's submission of the Baxter ANDA to the FDA constitutes an act of infringement of the '012 patent under 35 U.S.C § 271(e)(2)(A). Moreover, Baxter intends to commercially manufacture, import, use, offer for sale, or sell the Baxter ANDA product and/or induce or contribute to such conduct. Said actions would constitute infringement of the '012 patent under 35 U.S.C § 271(a) and/or (b).

47. Upon information and belief, Baxter was aware of the '012 patent prior to filing the Baxter ANDA, and its willful actions render this an exceptional case under 35 U.S.C. § 285.

48. The acts of infringement by Baxter set forth above will cause the Mallinckrodt Plaintiffs irreparable harm for which they have no adequate remedy at law, and will continue unless enjoined by this Court.

49. Baxter's submission of the Baxter ANDA to the FDA constitutes an act of infringement of the '265 patent under 35 U.S.C. § 271(e)(2)(A). In the event that Baxter commercially manufactures, imports, uses, offers for sale, or sells the Baxter ANDA product or induces such conduct, said actions would constitute infringement of the '265 patent under 35 U.S.C. § 271(a) and/or (b).

50. Upon information and belief, *inter alia*, Baxter's proposed labeling will instruct encourage, promote, and/or recommend the administration of the Baxter ANDA product to treat pain in a human subject weighing at least 50 kg by co-administering to the subject a therapeutically effective amount of a first pharmaceutical composition comprising about 500 mg to about 750 mg of acetaminophen and a therapeutically effective amount of a second pharmaceutical composition comprising an opioid analgesic, wherein the first pharmaceutical composition is administered to the subject intravenously, which co-administration will constitute direct infringement of at least Claim 1 of the '265 patent. Upon information and belief, if approved, the Baxter ANDA product will be used to treat mild to moderate pain in adult and pediatric patients two years and older, moderate to severe pain in conjunction with adjunctive opioid analgesics in the same population, and for the reduction of fever in adult and pediatric patients. Upon information and belief, Baxter will market its proposed products to hospitals, clinics, physicians, and other medical care providers and will promote, recommend, and/or encourage the practice of the steps of at least Claim 1 of the '265 patent.

51. The OFIRMEV® labeling includes instructions for administering OFIRMEV® to treat pain in a human subject weighing at least 50 kg by co-administering to the subject a therapeutically effective amount of a first pharmaceutical composition comprising about 500 mg to about 750 mg of acetaminophen and a therapeutically effective amount of a second pharmaceutical composition comprising an opioid analgesic, wherein the first pharmaceutical composition is administered to the subject intravenously. (*See* Exhibit F.)

52. For example, Section 1 of the OFIRMEV® labeling provides that "OFIRMEV (acetaminophen) injection is indicated for the . . . Management of moderate to severe pain with adjunctive opioid analgesics."

53. On information and belief, Baxter did not perform its own clinical trials, and instead will rely on the clinical trials referenced in the OFIRMEV® labeling for the Baxter ANDA product labeling.

54. Section 6.1 of the OFIRMEV® labeling reports on clinical trials in which patients were administered 650 mg OFIRMEV® every 4 hours. On information and belief, the Baxter ANDA product labeling will contain the same or substantially the same information concerning said trials.

55. Section 14.1 of the OFIRMEV® labeling describes acute pain studies in adults in which patients were administered 650 mg OFIRMEV® every 4 hours. The OFIRMEV® labeling reports that patients receiving OFIRMEV® experienced a statistically significant greater reduction in pain intensity over 24 hours compared to placebo. On information and belief, the Baxter ANDA product labeling will contain the same or substantially the same statements.

56. The OFIRMEV® labeling therefore instructs, recommends, promotes, and/or encourages medical care providers to practice the methods of at least Claim 1 of the ’265 patent. On information and belief, the Baxter ANDA product labeling will instruct, recommend, promote, and/or encourage medical care providers to practice the methods of at least Claim 1 of the ’265 patent.

57. The foregoing information in the OFIRMEV® labeling is essential for the safe and effective use of the drug, particularly given the warnings in the labeling concerning potential dosing errors. As the warning in the Highlights of Prescribing Information indicates, “[t]ake care when prescribing, preparing, and administering OFIRMEV Injection to avoid dosing errors which could result in accidental overdose and death.” The Highlights continue: “Acetaminophen has been associated with cases of acute liver failure, at times resulting in liver transplant and

death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed the recommended maximum daily limits . . . ."

58. Upon information and belief, the Baxter ANDA product will be administered to treat pain in a human subject weighing at least 50 kg by co-administering to the subject a therapeutically effective amount of a first pharmaceutical composition comprising about 500 mg to about 750 mg of acetaminophen and a therapeutically effective amount of a second pharmaceutical composition comprising an opioid analgesic, wherein the first pharmaceutical composition is administered to the subject intravenously, which co-administration will constitute direct infringement of at least Claim 1 of the '265 patent. Upon information and belief, this will occur at Baxter's active behest, and with Baxter's intent, knowledge, and encouragement. Upon information and belief, Baxter will actively induce, encourage, and abet this infringement with knowledge that it is in contravention of the Mallinckrodt Plaintiffs' rights under the '265 patent.

59. Baxter's submission of the Baxter ANDA to the FDA constitutes an act of infringement of the '265 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, Baxter intends to commercially manufacture, import, use, offer for sale, or sell the Baxter ANDA product and/or induce such conduct. Said actions constitute infringement of the '265 patent under 35 U.S.C. § 271(a) and/or (b).

60. Upon information and belief, Baxter was aware of the '265 patent prior to filing the Baxter ANDA, and its willful actions render this an exceptional case under 35 U.S.C. § 285.

61. The acts of infringement by Baxter set forth above will cause the Mallinckrodt Plaintiffs irreparable harm for which they have no adequate remedy at law, and will continue unless enjoined by this Court.

62. Baxter's submission of the Baxter ANDA to the FDA constitutes an act of infringement of the '238 patent under 35 U.S.C. § 271(e)(2)(A). In the event that Baxter commercially manufactures, imports, uses, offers for sale, or sells the Baxter ANDA product or induces such conduct, said actions would constitute infringement of the '238 patent under 35 U.S.C. § 271(a) and/or (b).

63. Upon information and belief, *inter alia*, Baxter will encourage, promote, and/or recommend the administration of the Baxter ANDA product to treat pain in a human subject weighing at least 50 kg by administering to the subject a therapeutically effective amount of a first pharmaceutical composition comprising about 500 mg to about 750 mg of acetaminophen, and repeating the administration at least once every four hours, wherein the pharmaceutical composition is administered to the subject intravenously, and wherein the therapeutic effect of the pharmaceutical composition is comparable to the standard of care treatment of 1000 mg of acetaminophen administered orally every 6 hours, which administration will constitute direct infringement of at least Claim 1 of the '238 patent. Upon information and belief, if approved, the Baxter ANDA product will be used to treat mild to moderate pain in adult and pediatric patients two years and older, moderate to severe pain in conjunction with adjunctive opioid analgesics in the same population, and for the reduction of fever in adult and pediatric patients. Upon information and belief, Baxter will market its proposed products to hospitals, clinics, physicians, and other medical care providers and will promote, recommend, and/or encourage the practice of the steps of at least Claim 1 of the '238 patent.

64. The OFIRMEV® labeling includes instructions for administering OFIRMEV® to treat pain in a human subject weighing at least 50 kg by co-administering to the subject a therapeutically effective amount of a first pharmaceutical composition comprising 650 mg of

acetaminophen, and repeating the administration at least once every four hours, wherein the pharmaceutical composition is administered to the subject intravenously. (*See* Exhibit F.)

65. On information and belief, Baxter did not perform its own clinical trials, and instead will rely on the clinical trials referenced in the OFIRMEV® labeling for the Baxter ANDA product labeling.

66. Section 6.1 of the OFIRMEV® labeling reports on clinical trials in which patients were administered 650 mg OFIRMEV® every 4 hours. On information and belief, the Baxter ANDA product labeling will contain the same or substantially the same information concerning said trials.

67. Section 14.1 of the OFIRMEV® labeling describes acute pain studies in adults in which patients were administered 650 mg OFIRMEV® every 4 hours. The OFIRMEV® labeling reports that patients receiving OFIRMEV® experienced a statistically significant greater reduction in pain intensity over 24 hours compared to placebo. On information and belief, the Baxter ANDA product labeling will contain the same or substantially the same statements.

68. The OFIRMEV® labeling therefore instructs, recommends, promotes, and/or encourages medical care providers to practice the methods of at least Claim 1 of the ’238 patent. On information and belief, the Baxter ANDA product labeling will instruct, recommend, promote, and/or encourage medical care providers to practice the methods of at least Claim 1 of the ’238 patent.

69. The foregoing information in the OFIRMEV® labeling is essential for the safe and effective use of the drug, particularly given the warnings in the labeling concerning potential dosing errors. As the warning in the Highlights of Prescribing Information indicates, “[t]ake care when prescribing, preparing, and administering OFIRMEV Injection to avoid dosing errors

which could result in accidental overdose and death." The Highlights continue: "Acetaminophen has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed the recommended maximum daily limits . . . ."

70. Upon information and belief, Baxter's ANDA product will be administered to treat pain in a human subject weighing at least 50 kg by administering to the subject a therapeutically effective amount of a first pharmaceutical composition comprising about 500 mg to about 750 mg of acetaminophen, and repeating the administration at least once every four hours, wherein the pharmaceutical composition is administered to the subject intravenously, and wherein the therapeutic effect of the pharmaceutical composition is comparable to the standard of care treatment of 1000 mg of acetaminophen administered orally every 6 hours, which administration will constitute direct infringement of at least Claim 1 of the '238 patent. Upon information and belief, this will occur at Baxter's active behest, and with Baxter's intent, knowledge, and encouragement. Upon information and belief, Baxter will actively induce, encourage, and abet this infringement with knowledge that it is in contravention of the Mallinckrodt Plaintiffs' rights under the '238 patent.

71. Baxter's submission of the Baxter ANDA to the FDA constitutes an act of infringement of the '238 patent under 35 U.S.C § 271(e)(2)(A). Moreover, Baxter intends to commercially manufacture, import, use, offer for sale, or sell the Baxter ANDA product and/or induce such conduct. Said actions would constitute infringement of the '238 patent under 35 U.S.C § 271(a) and/or (b).

72. Upon information and belief, Baxter was aware of the '238 patent prior to filing the Baxter ANDA, and its willful actions render this an exceptional case under 35 U.S.C. § 285.

73. The acts of infringement by Baxter set forth above will cause the Mallinckrodt Plaintiffs irreparable harm for which they have no adequate remedy at law, and will continue unless enjoined by this Court.

74. Baxter's submission of the Baxter ANDA to the FDA constitutes an act of infringement of the '834 patent under 35 U.S.C. § 271(e)(2)(A). In the event that Baxter commercially manufactures, imports, uses, offers for sale, or sells the Baxter ANDA product or induces such conduct, said actions would constitute infringement of the '834 patent under 35 U.S.C. § 271(a) and/or (b).

75. Upon information and belief, *inter alia*, Baxter will encourage, promote, and/or recommend the administration of the Baxter ANDA product to treat pain in a human subject weighing at least 50 kg by administering to the subject an intravenous acetaminophen formulation comprising about 650 mg of acetaminophen, and repeating the administration every four hours, wherein the subject receives a maximum daily dose of less than 4000 mg of acetaminophen per day, which administration will constitute direct infringement of at least Claim 1 of the '834 patent. Upon information and belief, if approved, the Baxter ANDA product will be used to treat mild to moderate pain in adult and pediatric patients two years and older, moderate to severe pain in conjunction with adjunctive opioid analgesics in the same population, and for the reduction of fever in adult and pediatric patients. Upon information and belief, Baxter will market its proposed products to hospitals, clinics, physicians, and other medical care providers and will promote, recommend, and/or encourage the practice of the steps of at least Claim 1 of the '834 patent.

76. The OFIRMEV® labeling includes instructions for administering OFIRMEV® to treat pain in a human subject weighing at least 50 kg by co-administering to the subject a

therapeutically effective amount of a first pharmaceutical composition comprising 650 mg of acetaminophen, and repeating the administration at least once every four hours, wherein the pharmaceutical composition is administered to the subject intravenously. (*See* Exhibit F.)

77. On information and belief, Baxter did not perform its own clinical trials, and instead will rely on the clinical trials referenced in the OFIRMEV® labeling for the Baxter ANDA product labeling.

78. Section 6.1 of the OFIRMEV® labeling reports on clinical trials in which patients were administered 650 mg of OFIRMEV® every 4 hours. On information and belief, the Baxter ANDA product will contain the same or substantially the same information concerning said trials.

79. Section 14.1 of the OFIRMEV® labeling describes acute pain studies in adults in which patients were administered 650 mg of OFIRMEV® every 4 hours. The OFIRMEV® labeling reports that patients receiving OFIRMEV® experienced a statistically significant greater reduction in pain intensity over 24 hours compared to placebo. On information and belief, the Baxter ANDA product labeling will contain the same or substantially the same statements.

80. The OFIRMEV® labeling therefore instructs, recommends, promotes, and/or encourages medical care providers to practice the methods of at least Claim 1 of the ’834 patent. On information and belief, the Baxter ANDA product labeling will instruct, recommend, promote, and/or encourage medical care providers to practice the methods of at least Claim 1 of the ’834 patent.

81. The foregoing information in the OFIRMEV® labeling is essential for the safe and effective use of the drugs, particularly given the warnings in the labeling concerning potential dosing errors. As the warning in the Highlights of Prescribing Information indicates,

"[t]ake care when prescribing, preparing, and administering OFIRMEV Injection to avoid dosing errors which could result in accidental overdose and death." The Highlights continue: "Acetaminophen has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed the recommended maximum daily limits . . . ."

82. Upon information and belief, Baxter's ANDA product will be administered to treat pain in a human subject weighing at least 50 kg by administering to the subject an intravenous acetaminophen formulation comprising about 650 mg of acetaminophen, and repeating the administration every four hours, wherein the subject receives a maximum daily dose of less than 4000 mg of acetaminophen per day, which administration will constitute direct infringement of at least Claim 1 of the '834 patent. Upon information and belief, this will occur at Baxter's active behest, and with Baxter's intent, knowledge, and encouragement. Upon information and belief, Baxter will actively induce, encourage, and abet this infringement with knowledge that it is in contravention of the Mallinckrodt Plaintiffs' rights under the '834 patent.

83. Baxter's submission of the Baxter ANDA to the FDA constitutes an act of infringement of the '834 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, Baxter intends to commercially manufacture, import, use, offer for sale, or sell the Baxter ANDA products and/or induce such conduct. Said actions would constitute infringement of the '834 patent under 35 U.S.C. § 271(a) and/or (b).

84. Upon information and belief, Baxter was aware of the '834 patent prior to filing ANDA No. 214331, and its willful actions render this an exceptional case under 35 U.S.C. § 285.

85. The acts of infringement by Baxter set forth above will cause the Mallinckrodt Plaintiffs irreparable harm for which they have no adequate remedy at law, and will continue unless enjoined by this Court.

COUNT I
(INFRINGEMENT OF THE '218 PATENT BY THE BAXTER ANDA PRODUCT)

86. Plaintiffs incorporate each of the preceding paragraphs 1 to 85 as if fully set forth herein.

87. Baxter's submission of the Baxter ANDA, including its Paragraph IV certification, constitutes infringement of the '218 patent by Baxter pursuant to 35 U.S.C. § 271(e)(2).

88. On information and belief, upon FDA approval of the Baxter ANDA, Baxter will infringe the '218 patent by manufacturing, using, offering to sell, or selling the Baxter ANDA Product in the United States, and/or importing the Baxter ANDA product into the United States, and by actively inducing and/or contributing to infringement by others, in violation of 35 U.S.C. § 271(a), (b), and/or (c).

89. On information and belief, Baxter had actual and constructive knowledge of the '218 patent prior to filing of the Baxter ANDA and acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '218 patent.

COUNT II
(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '218 PATENT BY THE BAXTER ANDA PRODUCT)

90. Plaintiffs incorporate each of the preceding paragraphs 1 to 89 as if fully set forth herein.

91. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

92. Plaintiffs are further entitled to a declaration that, if Baxter, prior to patent expiry, commercially manufactures, uses, offers for sale, or sells the Baxter ANDA product within the United States, imports the Baxter ANDA product into the United States, or induces or contributes to such conduct, Baxter would infringe the '218 patent under 35 U.S.C. § 271(a), (b), and/or (c).

93. Plaintiffs are entitled to an injunction restraining and enjoining Baxter and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States of any of the Baxter's ANDA Product until the expiration of the '218 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

94. Plaintiffs will be irreparably harmed by Baxter's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

COUNT III
(INFRINGEMENT OF THE '012 PATENT BY THE BAXTER ANDA PRODUCT)

95. The Mallinckrodt Plaintiffs incorporate each of the preceding paragraphs 1 to 94 as if fully set forth herein.

96. Baxter's submission of the Baxter ANDA constitutes infringement of the '012 patent pursuant to 35 U.S.C. § 271(e)(2).

97. Upon information and belief, upon FDA approval of the Baxter ANDA, Baxter will induce and/or contribute to infringement of at least Claim 1 of the '012 patent by making, using, offering to sell, or selling the Baxter ANDA product in the United States, and/or importing the Baxter ANDA product into the United States, in violation of 35 U.S.C. § 271.

98. Upon information and belief, upon FDA approval of the Baxter ANDA, doctors, nurses, and other medical professionals will directly infringe at least Claim 1 of the '012 patent by using the Baxter ANDA product, in violation of 35 U.S.C. § 271(a). Upon information and belief, Baxter's proposed labeling and promotion of the Baxter ANDA product will encourage, promote, and/or recommend a method of administering that product to treat pain or fever in an adult human or an adolescent human subject weighing at least 50 kg, in need thereof, by administering to the subject, by an intravenous route of administration, a therapeutically effective amount of a pharmaceutical composition comprising about 550 mg to about 800 mg of acetaminophen and repeating said administration at least once at an interval of about 3 to about 5 hours, which administration will constitute direct infringement of at least Claim 1 of the '012 patent. Additionally, Baxter will otherwise promote, encourage, and/or instruct use of the Baxter ANDA product for treating pain or fever in an adult human or an adolescent human subject weighing at least 50 kg, in need thereof, by administering to the subject, by an intravenous route of administration, a therapeutically effective amount of a pharmaceutical composition comprising about 550 mg to about 800 mg of acetaminophen and repeating said administration at least once at an interval of about 3 to about 5 hours.

99. Upon information and belief, this direct infringement will occur at Baxter's active behest, and with Baxter's intent, knowledge, and encouragement. Baxter will intentionally encourage infringement of at least Claim 1 of the '012 patent by making, using, offering to sell, or selling the Baxter ANDA product and by recommending and/or instructing use of the Baxter ANDA product. Furthermore, Baxter will intentionally encourage infringement of at least Claim 1 of the '012 patent at least by way of the labeling for the Baxter ANDA product which will contain recommendations and/or instructions for treating pain or fever in an adult human or an

adolescent human subject weighing at least 50 kg, in need thereof, by administering to the subject, by an intravenous route of administration, a therapeutically effective amount of a pharmaceutical composition comprising about 550 mg to about 800 mg of acetaminophen and repeating said administration at least once at an interval of about 3 to about 5 hours. Additionally, Baxter will otherwise promote, encourage, and/or instruct use of the Baxter ANDA product for treating pain or fever in an adult human or an adolescent human subject weighing at least 50 kg, in need thereof, by administering to the subject, by an intravenous route of administration, a therapeutically effective amount of a pharmaceutical composition comprising about 550 mg to about 800 mg of acetaminophen and repeating said administration at least once at an interval of about 3 to about 5 hours.

100. Upon information and belief, Baxter is aware of the '012 patent, which is listed in the Orange Book with respect to OFIRMEV®, and Baxter will actively induce, encourage, and abet this infringement with knowledge that such conduct is in contravention of the Mallinckrodt Plaintiffs' rights under the '012 patent, in violation of 35 U.S.C. § 271(b).

101. Upon information and belief, Baxter had actual and constructive knowledge of the application that later issued as the '012 patent prior to filing ANDA No. 214331 and acted without a reasonable basis for a good faith belief that they would not be liable for infringing the '012 patent upon its issuance.

COUNT IV
(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '012 PATENT BY THE BAXTER ANDA PRODUCT)

102. Plaintiffs incorporate each of the preceding paragraphs 1 to 101 as if fully set forth herein.

103. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

104. The Mallinckrodt Plaintiffs are entitled to a declaration that, if Baxter, prior to patent expiry, commercially manufactures, uses, offers for sale, or sells the Baxter ANDA product within the United States, imports the Baxter ANDA product into the United States, or induces or contributes to such conduct, Baxter would infringe the '012 patent under 35 U.S.C. § 271(a) and/or (b).

105. An actual controversy has arisen and now exists between the parties concerning whether Baxter will directly or indirectly infringe the '012 patent.

106. The Mallinckrodt Plaintiffs are entitled to an injunction restraining and enjoining Baxter and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States of any of the Baxter ANDA product until the expiration of the '012 patent, including any extensions and/or additional periods of exclusivity to which the Mallinckrodt Plaintiffs are or become entitled.

107. The Mallinckrodt Plaintiffs will be irreparably harmed by Baxter's infringing activities unless those activities are enjoined by this Court. The Mallinckrodt Plaintiffs do not have an adequate remedy at law.

COUNT V
(INFRINGEMENT OF THE '265 PATENT BY THE BAXTER ANDA PRODUCT)

108. Plaintiffs incorporate each of the preceding paragraphs 1 to 107 as if fully set forth herein.

109. Baxter's submission of ANDA No. 214331 constitutes infringement of the '265 patent pursuant to 35 U.S.C. § 271(e)(2).

110. Upon information and belief, upon FDA approval of ANDA No. 214331, Baxter will induce infringement of at least Claim 1 of the ’265 patent by making, using, offering to sell, or selling the Baxter ANDA product in the United States, and/or importing the Baxter ANDA product into the United States, in violation of 35 U.S.C. § 271.

111. Upon information and belief, upon FDA approval of ANDA No. 214331, doctors, nurses, and other medical professionals will directly infringe at least Claim 1 of the ’265 patent by using the Baxter ANDA product, in violation of 35 U.S.C. § 271(a). The Baxter ANDA product will be administered to treat pain in a human subject weighing at least 50 kg by co-administering to the subject a therapeutically effective amount of a first pharmaceutical composition comprising about 500 mg to about 750 mg of acetaminophen and a therapeutically effective amount of a second pharmaceutical composition comprising an opioid analgesic, wherein the first pharmaceutical composition is administered to the subject intravenously, which co- administration will constitute direct infringement of at least Claim 1 of the ’265 patent.

112. Upon information and belief, this direct infringement will occur at Baxter’s active behest, and with Baxter’s intent, knowledge, and encouragement. Baxter will intentionally encourage infringement of at least Claim 1 of the ’265 patent at least by way of the labeling for the Baxter ANDA product which will contain recommendations and/or instructions for treating pain in a human subject weighing at least 50 kg by co-administering to the subject a therapeutically effective amount of a first pharmaceutical composition comprising about 500 mg to about 750 mg of acetaminophen and a therapeutically effective amount of a second pharmaceutical composition comprising an opioid analgesic, wherein the first pharmaceutical composition is administered to the subject intravenously. Additionally, Baxter will otherwise promote, encourage, and/or instruct use of the Baxter ANDA product for treating pain in a

human subject weighing at least 50 kg by co-administering to the subject a therapeutically effective amount of a first pharmaceutical composition comprising about 500 mg to about 750 mg of acetaminophen and a therapeutically effective amount of a second pharmaceutical composition comprising an opioid analgesic, wherein the first pharmaceutical composition is administered to the subject intravenously.

113. Upon information and belief, Baxter is aware of the '265 patent, which is listed in the Orange Book with respect to OFIRMEV®, and Baxter will actively induce, encourage, and abet this infringement with knowledge that such conduct is in contravention of the Mallinckrodt Plaintiffs' rights under the '265 patent, in violation of 35 U.S.C. § 271(b). Upon information and belief, Baxter had actual and constructive knowledge of the application that later issued as the '265 patent prior to filing ANDA No. 214331 and acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '265 patent upon its issuance.

COUNT VI
(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '265 PATENT BY THE BAXTER ANDA PRODUCT)

114. Plaintiffs incorporate each of the preceding paragraphs 1 to 113 as if fully set forth herein.

115. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

116. The Mallinckrodt Plaintiffs are entitled to a declaration that, if Baxter, prior to patent expiry, commercially manufactures, uses, offers for sale, or sells the Baxter ANDA product within the United States, imports the Baxter ANDA product into the United States, or induces such conduct, Baxter would infringe the '265 patent under 35 U.S.C. § 271(a) and/or (b).

117. An actual controversy has arisen and now exists between the parties concerning whether Baxter will directly or indirectly infringe the '265 patent.

118. The Mallinckrodt Plaintiffs are entitled to an injunction restraining and enjoining Baxter and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States of any of the Baxter ANDA product until the expiration of the '265 patent, including any extensions and/or additional periods of exclusivity to which the Mallinckrodt Plaintiffs are or become entitled.

119. The Mallinckrodt Plaintiffs will be irreparably harmed by Baxter's infringing activities unless those activities are enjoined by this Court. The Mallinckrodt Plaintiffs do not have an adequate remedy at law.

COUNT VII
(INFRINGEMENT OF THE '238 PATENT BY THE BAXTER ANDA PRODUCT)

120. Plaintiffs incorporate each of the preceding paragraphs 1 to 119 as if fully set forth herein.

121. Baxter's submission of the Baxter ANDA constitutes infringement of the '238 patent pursuant to 35 U.S.C. § 271(e)(2).

122. Upon information and belief, upon FDA approval of the Baxter ANDA, Baxter will induce and/or contribute to infringement of at least Claim 1 of the '238 patent by making, using, offering to sell, or selling the Baxter ANDA product in the United States, and/or importing the Baxter ANDA product into the United States, in violation of 35 U.S.C. § 271.

123. Upon information and belief, upon FDA approval of the Baxter ANDA, doctors, nurses, and other medical professionals will directly infringe at least Claim 1 of the '238 patent

by using the Baxter ANDA product, in violation of 35 U.S.C. § 271(a). Upon information and belief, Baxter's proposed labeling and promotion of the Baxter ANDA product will encourage, promote, and/or recommend a method of administering that product to treat pain in a human subject, in need thereof, weighing at least 50 kg by administering to the subject a therapeutically effective amount of a pharmaceutical composition comprising about 500 mg to about 750 mg of acetaminophen and repeating the administration at least once every four hours, wherein the pharmaceutical composition is administered to the subject intravenously, and wherein the therapeutic effect of the pharmaceutical composition is comparable to the standard of care treatment of 1000 mg of acetaminophen administered orally every 6 hours, which administration will constitute direct infringement of at least Claim 1 of the '238 patent. Additionally, Baxter will otherwise promote, encourage, and/or instruct use of the Baxter ANDA product for treating pain in a human subject, in need thereof, weighing at least 50 kg by administering to the subject a therapeutically effective amount of a pharmaceutical composition comprising about 500 mg to about 750 mg of acetaminophen and repeating the administration at least once every four hours, wherein the pharmaceutical composition is administered to the subject intravenously, and wherein the therapeutic effect of the pharmaceutical composition is comparable to the standard of care treatment of 1000 mg of acetaminophen administered orally every 6 hours.

124. Upon information and belief, this direct infringement will occur at Baxter's active behest, and with Baxter's intent, knowledge, and encouragement. Baxter will intentionally encourage infringement of at least Claim 1 of the '238 patent by at least making, using, offering to sell, or selling the Baxter ANDA product and by recommending and/or instructing use of the Baxter ANDA product. Furthermore, Baxter will intentionally encourage infringement of at least Claim 1 of the '238 patent at least by way of the labeling for the Baxter ANDA product which

will contain recommendations and/or instructions for treating pain in a human subject, in need thereof, weighing at least 50 kg by administering to the subject a therapeutically effective amount of a pharmaceutical composition comprising about 500 mg to about 750 mg of acetaminophen and repeating the administration at least once every four hours, wherein the pharmaceutical composition is administered to the subject intravenously, and wherein the therapeutic effect of the pharmaceutical composition is comparable to the standard of care treatment of 1000 mg of acetaminophen administered orally every 6 hours. Additionally, Baxter will otherwise promote, encourage, and/or instruct use of the Baxter ANDA product for treating pain in a human subject, in need thereof, weighing at least 50 kg by administering to the subject a therapeutically effective amount of a pharmaceutical composition comprising about 500 mg to about 750 mg of acetaminophen and repeating the administration at least once every four hours, wherein the pharmaceutical composition is administered to the subject intravenously, and wherein the therapeutic effect of the pharmaceutical composition is comparable to the standard of care treatment of 1000 mg of acetaminophen administered orally every 6 hours.

125. Upon information and belief, Baxter is aware of the ’238 patent, which is listed in the Orange Book with respect to OFIRMEV®, and Baxter will actively induce, encourage, and abet this infringement with knowledge that such conduct is in contravention of the Mallinckrodt Plaintiffs’ rights under the ’238 patent, in violation of 35 U.S.C. § 271(b).

126. Upon information and belief, Baxter had actual and constructive knowledge of the application that later issued as the ’238 patent prior to filing ANDA No. 214331 and acted without a reasonable basis for a good faith belief that they would not be liable for infringing the ’238 patent upon its issuance.

COUNT VIII
(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '238 PATENT BY THE BAXTER ANDA PRODUCT)

127. Plaintiffs incorporate each of the preceding paragraphs 1 to 126 as if fully set forth herein.

128. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

129. The Mallinckrodt Plaintiffs are entitled to a declaration that, if Baxter, prior to patent expiry, commercially manufactures, uses, offers for sale, or sells the Baxter ANDA product within the United States, imports the Baxter ANDA product into the United States, or induces or contributes to such conduct, Baxter would infringe the '238 patent under 35 U.S.C. § 271(a) and/or (b).

130. An actual case or controversy has arisen and now exists between the parties concerning whether Baxter will directly or indirectly infringe the '238 patent.

131. The Mallinckrodt Plaintiffs are entitled to an injunction restraining and enjoining Baxter and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States of any of the Baxter ANDA product until the expiration of the '238 patent, including any extensions and/or additional periods of exclusivity to which the Mallinckrodt Plaintiffs are or become entitled.

132. The Mallinckrodt Plaintiffs will be irreparably harmed by Baxter's infringing activities unless those activities are enjoined by this Court. The Mallinckrodt Plaintiffs do not have an adequate remedy at law.

COUNT IX
(INFRINGEMENT OF THE '834 PATENT BY THE BAXTER ANDA PRODUCT)

133. Plaintiffs incorporate each of the preceding paragraphs 1 to 132 as if fully set forth herein.

134. Baxter's submission of the Baxter ANDA constitutes infringement of the '834 patent pursuant to 35 U.S.C. § 271(e)(2).

135. Upon information and belief, upon FDA approval of the Baxter ANDA, Baxter will induce and/or contribute to infringement of at least Claim 1 of the '834 patent by making, using, offering to sell, or selling the Baxter ANDA product in the United States, and/or importing the Baxter ANDA product into the United States, in violation of 35 U.S.C. § 271.

136. Upon information and belief, upon FDA approval of the Baxter ANDA, doctors, nurses, and other medical professionals will directly infringe at least Claim 1 of the '834 patent by using the Baxter ANDA product in violation of 35 U.S.C. § 271(a). Upon information and belief, Baxter's proposed labeling and promotion of the Baxter ANDA product will encourage, promote and/or recommend a method of administering that product to treat pain in a human subject weighing at least 50 kg by administering to the subject an intravenous acetaminophen formulation comprising about 650 mg of acetaminophen, and repeating the administration every four hours, wherein the subject receives a maximum daily dose of less than 4000 mg of acetaminophen per day, which administration will constitute direct infringement of at least Claim 1 of the '834 patent. Additionally, Baxter will otherwise promote, encourage, and/or instruct use of the Baxter ANDA product for treating pain in a human subject weighing at least 50 kg by administering to the subject an intravenous acetaminophen formulation comprising about 650 mg of acetaminophen, and repeating the administration every four hours, wherein the subject receives a maximum daily dose of less than 4000 mg of acetaminophen per day.

137. Upon information and belief, this direct infringement will occur at Baxter's active behest, and with Baxter's intent, knowledge, and encouragement. Baxter will intentionally encourage infringement of at least Claim 1 of the '834 patent by at least making, using, offering to sell, or selling the Baxter ANDA product and by recommending and/or instructing use of the Baxter ANDA product. Furthermore, Baxter will intentionally encourage infringement of at least Claim 1 of the '834 patent at least by way of the labeling for the Baxter ANDA product which will contain recommendations and/or instructions for treating pain in a human subject weighing at least 50 kg by administering to the subject an intravenous acetaminophen formulation comprising about 650 mg of acetaminophen, and repeating the administration every four hours, wherein the subject receives a maximum daily dose of less than 4000 mg of acetaminophen per day. Additionally, Baxter will otherwise promote, encourage, and/or instruct use of the Baxter ANDA product for treating pain in a human subject weighing at least 50 kg by administering to the subject an intravenous acetaminophen formulation comprising about 650 mg of acetaminophen, and repeating the administration every four hours, wherein the subject receives a maximum daily dose of less than 4000 mg of acetaminophen per day

138. Upon information and belief, Baxter is aware of the '834 patent, which is listed in the Orange Book with respect to OFIRMEV®, and Baxter will actively induce, encourage, and abet this infringement with knowledge that such conduct is in contravention of the Mallinckrodt Plaintiffs' rights under the '834 patent, in violation of 35 U.S.C. § 271(b).

139. Upon information and belief, Baxter had actual and constructive knowledge of the application that later issued as the '834 patent prior to filing ANDA No. 214331 and acted without a reasonable basis for a good faith belief that they would not be liable for infringing the '834 patent upon its issuance.

COUNT X
(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '834 PATENT BY THE BAXTER ANDA PRODUCT)

140. Plaintiffs incorporate each of the preceding paragraphs 1 to 139 as if fully set forth herein.

141. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

142. Plaintiffs are further entitled to a declaration that, if Baxter, prior to patent expiry, commercially manufactures, uses, offers for sale, or sells the Baxter ANDA product within the United States, imports the Baxter ANDA product into the United States, or induces or contributes to such conduct, Baxter would infringe the '834 patent under 35 U.S.C. § 271(a), (b), and/or (c).

143. Plaintiffs are entitled to an injunction restraining and enjoining Baxter and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States of any of the Baxter ANDA product until the expiration of the '834 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

144. Plaintiffs will be irreparably harmed by Baxter's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Baxter infringed and is infringing each of the Patents-in-Suit;

B. An order issued pursuant to 35 U.S.C. § 271(e)(4) that the effective date of any approval of the Baxter ANDA shall not be earlier than the expiration date of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

C. A declaration that if Baxter, prior to patent expiry, commercially manufactures, uses, offers to sell, or sells the Baxter ANDA Product within the United States, imports the Baxter ANDA product into the United States, or induces or contributes to such conduct, Baxter would infringe the Patents-in-Suit;

D. A preliminary and permanent injunction restraining and enjoining Baxter and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States of any of the Baxter ANDA product until the expiration of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

E. The Plaintiffs be awarded monetary relief if Baxter commercially manufactures, uses, offers for sale, or sells its generic version of Plaintiffs' OFIRMEV® brand product, or any other product that infringes or induces or contributes to the infringement of the Patents-in-Suit, within the United States before the latest expiration date of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

F. A declaration that this is an exceptional case and an award to Plaintiffs of their reasonable expenses including attorneys' fees pursuant to 35 U.S.C. § 285;

G. An award to Plaintiffs of costs in this action; and

H. Such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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